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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,637	09/09/2003	William Francis Seip	P-5188 D1	4711
26253	7590	11/30/2006	EXAMINER	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			BOWERS, NATHAN ANDREW	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/658,637	SEIP, WILLIAM FRANCIS
	Examiner Nathan A. Bowers	Art Unit 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 September 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 and 30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-23 and 30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____. 	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-14 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoermer (US 4976931) in view of Kashiba (US 6153422) and Nishimura (6756018).

With respect to claims 1, 2, 14, 16-18, Stoermer discloses an apparatus and method for generating an anaerobic environment within a container (Figure 3:32). A carbon dioxide generating material (Figure 2:14) is placed within a wrap (Figure 2:10) that forms an air barrier. The wrap is then placed into the container, and the container is sealed. This is disclosed in column 3, line 44 to column 4, line 22. When a portion of the wrap is removed by tearing along line 22, carbon dioxide generated within the wrap is allowed to diffuse into the container volume, thereby contributing to the creation of an anaerobic environment. Stoermer, however, does not expressly disclose that the carbon dioxide generating material is positioned within an air-permeable bag that is in turn positioned within the air barrier wrap. Stoermer does not disclose the use of a heat generating material capable of interacting with the carbon dioxide generating material.

Kashiba discloses a heat generating material that reacts with oxygen in air in order to create an anaerobic environment for cell culture. Kashiba states that the heat generating material is positioned in air-permeable bags that facilitate interaction with oxygen in the surrounding environment. This is described in column 1, lines 10-15, column 1, line 49 to column 2, line 1, column 3, lines 5-8, and column 5, lines 35-47.

Stoermer and Kashiba are analogous art because they are from the same field of endeavor regarding devices designed to create anaerobic conditions during cell culture.

At the time of the invention, it would have been obvious to position the carbon dioxide generating materials disclosed by Stoermer directly in an air-permeable bag that is in turn placed within the disclosed air barrier wrap. Kashiba indicates that bags characterized by excellent breathability are known in the art as means by which to regulate the multidirectional diffusion of gases in a controlled manner. An air permeable bag would also be used as a positioning means capable of ensuring that the carbon dioxide generating materials are restricted to a desired location, and not scattered across the interior of the air barrier wrap during handling.

At the time of the invention, it would also have been obvious to incorporate a heat generating means into the invention of Stoermer in order to provide a mechanism to induce the generation of carbon dioxide. Heat generating materials that absorb oxygen are well known in the anaerobic culture art, as evidenced by Kashiba. In the invention of Stoermer, water is used to initiate a reaction that produces carbon dioxide. It would have been apparent to one of ordinary skill in the art to replace the water system of Stoermer with the heat generating materials of Kashiba as a mechanism to set off carbon dioxide production. Nishimura teaches in column 3, lines 15-49 and column 4, lines 7-15 that solid carbon dioxide generating compounds (such as sodium bicarbonate) produce carbon dioxide effectively when heated. Nishimura teaches that a large amount of carbon dioxide is produced through the heating of a relatively small amount solid material. This heating arrangement (combining Stoermer's carbon dioxide generating material with Kashiba's heat generating material) is especially beneficial

because it does not require the use of liquids, which are often times messy and require the use of a complicated system of interconnected chambers.

With respect to claims 3, 9, 10, 19 and 20, Stoermer, Kashiba and Nishimura disclose the apparatus and method set forth in claims 2 and 18 as set forth in the 35 U.S.C. 103 rejection above. Although Stoermer and Kashiba do not expressly disclose a strategy for integrating a heat generating material with a carbon dioxide generating material into the same air-permeable bag, it would have been obvious to accomplish this using whatever arrangement produces the best results. Stoermer discloses in Figure 2 that it is known to utilize two separate solid tablets (13, 14) positioned side by side. Kashiba discloses that it is known in the art to utilize a single compound capable of both generating heat and producing carbon dioxide upon reaction with oxygen (see column 5, lines 35-38). Accordingly, it would have been obvious to position the heat and carbon dioxide generating materials adjacent to each other as separate tablets in the air permeable bag. It would also have obvious to mix the carbon dioxide generating composition with the heat generating composition to form a single unit.

With respect to claims 4-8, 11-13 and 21-23, Stoermer, Kashiba and Nishimura disclose the apparatus and method set forth in claims 2, 3, 10 and 18 as set forth in the 35 U.S.C. 103 rejection above. Stoermer additionally indicates in column 6, lines 31-54 that the carbon dioxide generating material is sodium bicarbonate. Stoermer also states that the carbon dioxide generating material includes citric acid and/or ascorbic acid.

2) Claims 1-4, 6-14 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasugai (US 4605617) in view of Kashiba (US 6153422) and Nishimura (6756018).

With respect to claims 1, 2, 14, 16-18, Kasugai discloses an apparatus and method for generating an anaerobic environment within a container (1). A carbon dioxide generating material (4, 5) is placed within an air permeable bag (2,3) that is in turn placed within the container. The container is sealed using a clip (8). This is disclosed in column 5, lines 40-60. Column 4, lines 41-50 indicate that prior to introduction into the container, the gas permeable bag is wrapped by a gas impermeable film. On use, the film is cut open, and gases within the container are allowed to diffuse through the permeable bag. Carbon dioxide generated within the bag is allowed to diffuse into the container volume, thereby contributing to the creation of an anaerobic environment. Kasugai, however, does not disclose the use of a heat generating material capable of interacting with the carbon dioxide generating material.

Kashiba discloses a heat generating material that reacts with oxygen in air in order to create an anaerobic environment for cell culture. Kashiba states that the heat generating material is positioned in air-permeable bags that facilitate interaction with oxygen in the surrounding environment. This is described in column 1, lines 10-15, column 1, line 49 to column 2, line 1, column 3, lines 5-8, and column 5, lines 35-47.

Kasugai and Kashiba are analogous art because they are from the same field of endeavor regarding devices designed to create anaerobic conditions during cell culture.

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At the time of the invention, it would also have been obvious to incorporate a heat generating means into the gas permeable bag disclosed by Kasugai in order to provide a mechanism to stimulate the generation of carbon dioxide. Nishimura teaches in column 3, lines 15-49 and column 4, lines 7-15 that solid carbon dioxide generating compounds (such as sodium bicarbonate) produce carbon dioxide effectively when heated. Nishimura teaches that a large amount of carbon dioxide is produced through the heating of a relatively small amount solid material. Heat generating materials that absorb oxygen are well known in the anaerobic culture art, as evidenced by Kashiba. By combining Kasugai's carbon dioxide generating material with Kashiba's heat generating material, one would provide a system in which carbon dioxide is produced in an effective manner upon contact with oxygen.

With respect to claims 3, 9, 10, 19 and 20, Kasugai, Kashiba and Nishimura disclose the apparatus and method set forth in claims 2 and 18 as set forth in the 35 U.S.C. 103 rejection above. Although Kasugai and Kashiba do not expressly disclose a strategy for integrating a heat generating material with a carbon dioxide generating material into the same air-permeable bag, it would have been obvious to accomplish this using whatever arrangement produces the best results. Accordingly, it would have been obvious to position the heat and carbon dioxide generating materials adjacent to each other as separate entities in the air permeable bag. It would also have obvious to mix the carbon dioxide generating composition with the heat generating composition to form a single unit.

With respect to claims 4, 6-8, 11-13 and 21-23, Kasugai, Kashiba and Nishimura disclose the apparatus and method set forth in claims 2, 3, 10 and 18 as set forth in the 35 U.S.C. 103 rejection above. Kasugai additionally indicates in column 4, lines 18-25 that the carbon dioxide generating material is sodium carbonate. Sodium carbonate and sodium bicarbonate are considered to be functional equivalents in the generation of carbon dioxide. Stoermer also states that the carbon dioxide generating material includes ascorbic acid.

3) Claims 15 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoermer (US 4976931) in view of Kashiba (US 6153422) and Nishimura (6756018) as applied to claims 14 and 16, and further in view of Ainsworth (US 6299774).

Stoermer, Kashiba and Nishimura disclose the apparatus and method set forth in claims 14 and 16 as set forth in the 35 U.S.C. 103 rejection above. Stoermer additionally discloses that the container includes a lid (Figure 3:33) operated by a bracket (Figure 3:34) and screw (Figure 3:35) that inherently could be used to relieve pressure within the container. Stoermer, however, does not expressly describe this intended use.

Ainsworth discloses an anaerobic digester system in which carbon dioxide gases are added and recycled through the fermentation tank. Column 8, lines 12-35 disclose that the tank includes pressure relief valves capable of controlling the pressure within the tank.

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At the time of the invention, it would have been obvious to either use the lid disclosed by Stoermer to regulate pressure within the container or incorporate additional pressure relief valves into the container. This would ensure that if excessive amounts of carbon dioxide are produced by the generating materials, the container is not subjected to intolerable pressure levels. This is beneficial because high pressure can often result in disturbed microorganism growth and damage to the container structure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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